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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,869	04/05/2006	Alan Michael Chapman	PG4979USw	9343
23347	7590	03/17/2008		
GLAXOSMITHKLINE CORPORATE INTELLECTUAL PROPERTY, MAI B475 FIVE MOORE DR., PO BOX 13398 RESEARCH TRIANGLE PARK, NC 27709-3398			EXAMINER DAVIS, BRIAN J	
			ART UNIT 1621	PAPER NUMBER
			NOTIFICATION DATE 03/17/2008	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/532,869	<b>Applicant(s)</b> CHAPMAN ET AL.	
	<b>Examiner</b> Brian J. Davis	<b>Art Unit</b> 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15, 17, 18 and 22-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-6, 8-14 and 22-24 is/are allowed.
- 6) ☒ Claim(s) 15 is/are rejected.
- 7) ☒ Claim(s) 7, 15, 17 and 18 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/26/05</u> .                                                 | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restriction***

Applicant's election, without traverse, of the claims of Group I (12/12/07 Response) and the species defined in the 2/6/08 Response as the group and species, respectively, elected to begin prosecution is acknowledged. The election/restriction is hereby made FINAL.

For clarity of the record, the examiner notes that applicant has canceled all claims which are not part of Group I.

### ***Claim Objections***

Claim 7 is objected to because of the following informalities: the claim does not end with a period (after the structures). Claims must begin with a capital letter and end with a period. MPEP 608.01(m).Appropriate correction is required. Applicant's assistance is respectfully requested in correcting any other minor errors of grammar or spelling which may be present in the claims.

Claims 15, 17 and 18 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The method, compositions, and combinations of claims 15, 17 and 18 do not and cannot further limit

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the *compounds* of claim 1. Additionally, in claims 17 and 18, the exact meaning of the term “other therapeutic ingredients” is unclear because it is undefined.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 15 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating asthma, depression, congestive heart failure, etc. does not reasonable provide for the prophylaxis (i.e. the prevention) of any of them. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

With regard to rejections under 35 USC 112, first paragraph, the following factors are considered (*In re Wands* 8 USPQ 2d 1400, 1404 (CAFC 1988)): a) Breadth of claims; b) Nature of invention; c) State of the prior art; d) Level of ordinary skill in the art; e) Level of predictability in the art; f) Amount of direction and guidance provided by the inventor; g) Working examples and; h) Level of experimentation needed to make or use the invention based on the content of the disclosure.

a) The claims are quite broad: “A method for the prophylaxis or treatment of a clinical condition in a mammal, for which a selective  $\beta_2$ -adrenoreceptor agonist...”. One of the common definitions of the term prophylaxis is, of course, *prevention*.

b,c) The nature of the invention is determined in part by the state of the prior art.

Even a cursory perusal of the teachings of the medicinal arts reveals that they have not advanced to the point where complex conditions such as asthma, depression, etc. in general can be said to be preventable. The art, in general, teaches, instead, that what can be prevented with regard to such disorders are their associated symptoms.

d) The level of skill in the art is considered to be relatively high.

e) The level of predictability in the art is considered to be relatively low.

The basis of all modern medicine and biology is, of course, chemistry. Yet even under the best of circumstances, and several hundred years after Lavoisier laid the foundations of its modern practice, chemistry remains an experimental science. Neither the medicinal/biological arts nor the chemical arts upon which they are based have advanced to the point where certainty has replaced the need for clinical and/or laboratory experimentation.

f,g) The amount of direction provided by the inventor is considered to be determined by the specification and the working examples. Applicant's data do not demonstrate that the instant compounds prevent asthma, depression, etc.

h) Regardless of the amount of experimentation involved, applicant's claims to prophylaxis are not believable in light of the present understanding of the above diseases/conditions in the contemporary medicinal arts. It is settled case law that allegations of utility that are not believable in light of the contemporary knowledge in the art must be substantiated by acceptable evidence or stricken from the specification. In

re Ferns, 163 USPQ 609 (CCPA 1969; Ex Parte Moore, 128, USPQ 8 (BPAI 1960); In re Hozumi, 226, USPQ 353 (Comr. Dec. 1985); MPEP 706.03(c).

### ***Allowable Subject Matter***

The elected species has been searched and is deemed free of the prior art. The search was therefor expanded as called for under current Office Markush examination practice, a compound-by-compound search. This resulted in all remaining species being searched.

Claims 1-6, 8-14 and 22-24 are allowed. The following is a statement of reasons for the indication of allowable subject matter:

As a representative example of the closest prior art, EP 162576 is cited. The reference appears in applicant's IDS. EP 162576 teaches compounds (abstract; page 1, beginning second full paragraph) structurally related to those of the instant invention, however, it neither teaches nor suggests the instant set of compounds.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Davis whose telephone number is 571-272-0638. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne (Bonnie) Eyler can be reached at 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian J. Davis/  
Primary Examiner, Art Unit 1621  
3/2/08